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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,798	10/18/2000	Xavier Paliard	PP01521.101	3092

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EXAMINER	
LI, QIAN J	

ART UNIT	PAPER NUMBER
1632	11

DATE MAILED: 11/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/673,798	Applicant(s) PALIARD, XAVIER	
	Examiner Q. Janice Li	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 10-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 10-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The amendment filed on August 28, 2002 has been entered as Paper # 11. Claims 8 and 9 have been canceled. Claims 1-7 and 10-29 are pending and under current examination.

Unless otherwise indicated, previous rejections that rendered moot in view of the amendment or new grounds of rejections to pending claims will not be reiterated.

Drawings

The formal drawing is missing from the file of the application. Applicants are invited to kindly resubmit the formal drawings.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for enhancing a humoral immune response to viral and tumor antigens by intramuscular or intradermal injection of nucleic acids expressing immunogens and the BLC, does not reasonably provide enablement for enhancing a cytotoxic T lymphocyte response to any antigen. The specification does not enable any

person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

In paper #10, the applicants fail to respond to the issue raised in paper #9 with regard to the type of the immune response enhanced, the cited reference of *Gunn et al* (Nature 1998 Feb 19;391:799) that BLC would induce antibody response, but not cytotoxic T cell response; and the specification fails to provide evidence to the contrary, thus, the specification fails to support the full scope of the claims. Therefore, the rejection stands.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 and 10-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite because of the claim recitation "DNA immunogen". The specification does not define the term, which reads on any DNA molecule including those unrelated to tumor or infectious antigens that is capable of triggering an immune response by itself, thus, the metes and bounds of the claims are unclear. In view of the teachings as a whole in the specification, the term seems to mean as defined in claim 2 or 7, i.e. a polynucleotide encoding an immunogen, this should be made clear in the base claim.

The claims are vague and indefinite because of the claim recitation "a B lymphocyte chemokine", which could reads on any B lymphocyte associated cytokine, thus, the metes and bounds of the claims are unclear. If applicants intend to claim the particular cytokine in the reference of *Gunn et al*, the proper term appears to be "B-lymphocyte chemoattractant (BLC)".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 11-13, 16, 17, 21, 25, and 27-29 stand rejected under 35 U.S.C. 102(e) as being anticipated by *Hurwitz et al* (US 5,846,546).

In paper #9, applicants argue that Hurwitz plainly teaches that when present, MIP is included for its antiviral chemotherapeutic effects, and it is a far cry from suggesting that chemokines enhance the immune response to a DNA immunogen.

The argument has been fully considered but found not persuasive for reasons of record and following.

Hurwitz et al clearly teach a method for induce an immune response to a viral antigen using a recombinant viral vector encoding a viral antigen and additionally comprising a chemokine such as MIP1α (2nd paragraph column 29), the chemokines are clearly taught to be used in the method. MPEP 2112.01 instructs that "PRODUCTS OF IDENTICAL CHEMICAL COMPOSITION CAN NOT HAVE MUTUALLY EXCLUSIVE PROPERTIES.' A CHEMICAL COMPOSITION AND ITS PROPERTIES ARE INSEPARABLE". THEREFORE, IF THE PRIOR ART TEACHES THE IDENTICAL CHEMICAL STRUCTURE, THE PROPERTIES APPLICANT DISCLOSES AND/OR CLAIMS ARE NECESSARILY PRESENT. *IN RE* SPADA, 911 F.2D 705, 15 USPQ2D 1655, 1658 (FED. CIR. 1990). It is a general rule that merely discovering and claiming a new benefit to an old process cannot render the process again patentable. *In re Woodruff* 919 F. 2d 1575, 1577-78, 16 USPQ2d 1934, 1936-37 (Fed. Cir. 1990); *In re Swinehart*, 439 F. 2d 210, 213, 169 USPQ 226, 229 (CCPA 1971); and *Ex Parte Novitski*, 26 USPQ2d 1389, 1391 (Bd. Pat. App. & Int. 1993).

Therefore, the rejection stands.

Claims 11-13, 16, 17, 21, 23-29 stand rejected under 35 U.S.C. 102(e) as being anticipated by *Selby et al* (US 6,355,247).

In paper #9, applicants argue that Selby et al. fails to describe, demonstrate induction of an antibody responses at all.

The argument has been fully considered but found not persuasive for reasons of record and following.

First, the claims are not limited to antibody response. Second, the composition used in the method taught by *Selby et al* meets the claim limitation as comprising a

chemokine or a polynucleotide encoding such and a viral antigen, therefore, it would intrinsically induce an antibody response. Again, MPEP 2112.01 instructs that "PRODUCTS OF IDENTICAL CHEMICAL COMPOSITION CAN NOT HAVE MUTUALLY EXCLUSIVE PROPERTIES.' A CHEMICAL COMPOSITION AND ITS PROPERTIES ARE INSEPARABLE". THEREFORE, IF THE PRIOR ART TEACHES THE IDENTICAL CHEMICAL STRUCTURE, THE PROPERTIES APPLICANT DISCLOSES AND/OR CLAIMS ARE NECESSARILY PRESENT. *IN RE* SPADA, 911 F.2D 705, 15 USPQ2D 1655, 1658 (FED. CIR. 1990).

Therefore, the rejection stands.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8, 10-21, and 23-29 stand rejected under 35 U.S.C. 103(a) as being unpatentable over *Hurwitz et al* (US 5,846,546) and *Selby et al* (US 6,355,247) as applied to claims 1-8, 10-13, 16, 17, 21, 23-29 above, and further in view of *DeVico et al* (US 6,214,540).

In paper #9, applicants argue that none of the references describe or demonstrate enhancing the immune response to a DNA immunogen using chemokine. And reiterated arguments under 102 rejection for Hurwitz, Selby, and further argue DeVico is directed to the use of chemokines themselves as therapeutics for HIV.

The argument has been fully considered but found not persuasive for reasons of record and following.

These references are constructed to show that it is known for one skilled artisan to use variations in scheduling chemokine administration during therapy for viral infection. *Hurwitz et al and Selby et al* teach administration of two components together, *Hurwitz* also teach that chemokine could be administered further or in addition to the immunogen. *DeVico et al* teach using chemokines for HIV therapy including using chemokine protein and nucleic acid encoding chemokines (section 4.4.1). And how one could personalize the treatment.

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods taught by *Hurwitz et al, Selby et al*, and DeVico et al by administering the immunogen and chemokine together or separate with a reasonable expectation of success because even chmokine alone could achieve a therapeutic effect. The ordinary skilled artisan would have been motivated to modify the method for enhanced immune response against virus and tumor. Thus, the claimed invention as a whole was clearly *prima facie* obvious in the absence of evidence to the contrary. It is noted that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

With regard to using the chemokine for enhancing immunization, again, it is a general rule that merely discovering and claiming a new benefit to an old process cannot render the process again patentable. *In re Woodruff* 919 F. 2d 1575, 1577-78, 16 USPQ2d 1934, 1936-37 (Fed. Cir. 1990); *In re Swinehart*, 439 F. 2d 210, 213, 169 USPQ 226, 229 (CCPA 1971); and *Ex Parte Novitski*, 26 USPQ2d 1389, 1391 (Bd. Pat. App. & Int. 1993).

Therefore, the rejection stands.

Claims 11-13, 16, 17, 21, 27, and 29 are newly rejected under 35 U.S.C. 102(e) as being unpatentable over *Chandrashekar et al* (US 6,383,774) in view of *Hurwitz et al* (US 5,846,546).

Chandrashekar et al teach an immunogenic composition comprising a nucleic acid encoding a parasitic immunogen and a method for administering such to a mammal including human to protect animals from disease caused by parasitic nematodes (abstract). Although the focus of *Chandrashekar et al* is for parasite infection, not immunization for viral infection, they clearly aware of immunization for other antigens. For example, they teach that the adjuvant chemokines, particularly MIP-1α (1st paragraph column 26) used with the DNA immunogen is capable of enhancing an immune response to an (any) antigen (1st paragraph column 26).

Hurwitz et al clearly teach a method for induce an immune response to a viral antigen using a recombinant viral vector encoding a viral antigen and additionally comprising a chemokine MIP1α (2nd paragraph column 29).

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods taught by *Hurwitz et al,* and *Chandrashekar et al* by administering an antigen of choice such as an viral DNA immunogen and a chemokine with a reasonable expectation of success. Thus, the claimed invention as a whole was clearly *prima facie* obvious in the absence of evidence to the contrary.

Applicants argue in paper #9 that *Chandrashekar et al* do not teach a viral antigen. However, it is noted that *Chandrashekar et al* teach it is known in the art that a specific antigen when administered to the animal would induce an immune response (column 2, lines 36-45), that the parasites are considered belong to difficult antigens in inducing a protective immune response, that many chemokines would enhance immune response in general to an (any) antigen (column 26, lines 3-4). Further, in the response under 35 USC 112 § 1st paragraph, applicants acknowledge that the method would enhance immune response to multiple antigens.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11-13, 16, 17, 21, and 23-29 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 5-14, and 16-19 of U.S. Patent No. 6,355,247. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims encompass the claims of cited patent.

In paper #9, applicants fail to address the instant rejection, therefore, for reasons of record, the rejection stands.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942. The examiner can normally be reached on 8:30 am - 5 p.m., Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of formal matters can be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235. The faxing of such papers must conform to the notice published in the Official Gazette 1096 OG 30 (November 15, 1989).

Q. Janice Li
Examiner
Art Unit 1632

QJL
November 15, 2002

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER